

***Remarks***

Reconsideration of this Application is respectfully requested.

***I. Status Of The Claims And Support For The Amendment***

Claims 1, 2, 4, 9, 10 and 12 have been amended, claim 47 has been canceled without prejudice to or disclaimer of the subject matter therein, and new claims 48 and 49 have been added. Support for the amendments is found in the present specification. No new matter has been added by these amendments, and entry of these amendments is respectfully requested.

***II. Documents NPL26 and NPL27 Should Be Considered***

At page 3 of the Office Action, the Examiner explained documents NPL26 and NPL27, listed on the Form SB/08/B filed October 15, 2008 had not been considered, because "[r]eferences NPL 26 and NPL 27 could not be found among the submitted documents."

Documents NPL26 and NPL27 were submitted with the information disclosure statement filed October 15, 2008, and today the undersigned verified that each of documents NPL26 and NPL27 are presently in the electronic application file on Private PAIR for the present application. Applicants respectfully request that the Examiner locate documents NPL26 and NPL27 on PAIR, and indicate on Form SB/08/B that documents NPL26 and NPL27 have been considered.

***III. The Rejection Under 35 U.S.C. § 101 Should Be Withdrawn***

At page 4 of the Office Action, the Examiner rejected claims 4 and 12 under 35 U.S.C. § 101, "because the claimed invention is directed to non-statutory subject matter." The Examiner stated:

The claims, as recited read on host cells still attached to an animal or human, including any eukaryotic cell. There is no limitation wherein the host cells are isolated or in culture, therefore the claims read on transfected cells in a human, and thus are not patentable subject matter. The rejection could be overcome by adding a limitation wherein the host cells are isolated or in culture.

Applicants respectfully traverse this rejection. However, solely in an effort to facilitate prosecution, claims 4 and 12 have been amended herein to recite that the cell is "isolated." As a result of this amendment, it is believed that the ground for this rejection has been obviated. Applicants respectfully request that this objection be reconsidered and withdrawn.

***IV. The Rejection Of Claims 4 and 12 Under 35 U.S.C. § 112, First Paragraph, For Lack Of Enablement, Should Be Withdrawn***

At page 4 of the Office Action, the Examiner rejected claims 4 and 12 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. Applicants respectfully traverse this rejection.

At page 5 of the Office Action, the Examiner explained that "making and using isolated host cells in culture in such areas as proteomics, functional genomics, cell based high throughput assays, toxicology screening and large-scale protein production . . ." is enabled. At page 6 of the Office Action, the Examiner stated that expressing the claimed

gene regulation system in transgenic animals and using the claimed gene regulation system in vivo in gene therapy is not enabled.

At page 8 of the Office Action, the Examiner stated:

[T]his rejection could be overcome by amending the claims to recite, for example "An isolated host cell . . ." because such an amendment would clarify that the claims are directed only to host cells which are to be made and used in culture as described in context 1) above [referring to making and using isolated host cells in culture].

Applicants respectfully disagree with this rejection. However, solely in an effort to facilitate prosecution, claims 4 and 12 have been amended herein to recite that the cell is "isolated." Applicants maintain, however, that any use of the isolated cell of claims 4 and 12 is enabled, and that enablement of the isolated cell of claims 4 and 12 is not limited to the list of applications discussed by the Examiner in the last paragraph of page 5 of the Office Action.

As a result of the amendment of claims 4 and 12 herein, it is believed that the ground for this rejection has been obviated. Applicants respectfully request that this objection be reconsidered and withdrawn.

***V. The Rejection Of Claims 3 and 11 Under 35 U.S.C. § 112, First Paragraph, For Lack Of Enablement, Should Be Withdrawn***

At page 8 of the Office Action, the Examiner rejected claims 3 and 11 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. Applicants respectfully traverse this rejection.

At page 8 of the Office Action, the Examiner stated:

Claims 3 and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a virus comprising:

- (a) the multiple gene regulation system of claim 1, where the system comprises one or more polynucleotides encoding a receptor complex and a polynucleotide comprising: an exogenous or endogenous polynucleotide and a response element; and
- (b) the multiple inducible gene regulation system of claim 9 wherein the system comprises a plurality of individually operable gene regulation systems wherein each individually operable gene regulation system comprises a polynucleotide comprising: an exogenous or endogenous gene; and a response element

does not reasonably provide enablement for:

- (c) the multiple gene regulation system of claim 1 wherein the system comprises a ligand; and
- (d) the multiple inducible gene regulation system of claim 9 wherein the system comprises a plurality of individually operable gene regulation systems wherein each individually operable gene regulation system comprises one or more receptor complexes and a ligand.

Independent claims 1 and 9 have been amended herein to delete recitation of "a ligand." Accordingly, claims 3 and 11, which depend from claims 1 and 9, respectively, do not require that the virus recited in claims 3 and 11 contains a ligand. As a result of the amendment of claims 3 and 11 herein, it is believed that the ground for this rejection has been obviated. Applicants respectfully request that this objection be reconsidered and withdrawn.

***VI. The Rejection Of Claims 1-4, 7-12, 15 and 47 Under 35 U.S.C. § 112, First Paragraph, For Lack Of Written Description, Should Be Withdrawn***

At page 10 of the Office Action, the Examiner rejected claims 1-4, 7-12, 15 and 47 under 35 U.S.C. § 112, first paragraph, for lack of written description. Applicants respectfully traverse this rejection.

At page 13 of the Office Action, the Examiner stated:

[T]he Lepidopteran/Dipteran and Lepidopteran/Homopteran receptor schemes (of the Group H family of receptors) but not the full breadth of the claims meet the written description provision of 35 U.S.C. 112, first paragraph.

In leading up to that conclusion, at page 12 of the Office Action, the Examiner stated:

Applicants' teachings are an invitation to experiment to design, identify and isolate appropriate receptor/ligand pairs which act orthogonally; the disclosure does not provide evidence that Applicants were in possession of such. Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features.

Applicants respectfully disagree. The test for written description is whether the description provides that the inventors were in possession of the claimed invention. *See M.P.E.P. § 2163.02* (citations omitted). Here, that test is met, because the present application clearly establishes that the inventors were in possession of the presently claimed invention. Moreover, it is not necessary for an applicant to have reduced a claimed invention to practice, in order to have described the invention. *See Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006), where the Federal Circuit stated:

[W]e hold, in accordance with our prior case law, that (1) examples are not necessary to support the adequacy of a written description (2) the written description standard may be met (as it is here) even where actual reduction to practice of an invention is absent; and (3) there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.

Applicants respectfully request that this rejection be reconsidered and withdrawn.

***Conclusion***

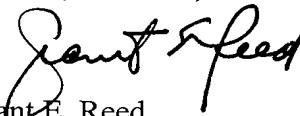
All of the stated grounds of objection and rejection have been properly traversed or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw the presently outstanding rejections. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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